5. 510(k) Summary as required by 21 CFR§807.92(c)

510(k) Owner: FCI SAS (France Chirurgie Instrumentation)
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Date: July 15, 2013

JUL 29 2013

Trade Name: OphtaCath® Unilateral Kit

Common name: Lacrimal balloon catheter

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device
The OphtaCath® lacrimal balloon catheter is substantially equivalent to the LacriCATH lacrimal balloon catheter marketed by Quest Medical, Inc. 510(k) Premarket Notification Number: K113867, FDA Product Code OKS.

The OphtaCath® is only available in kit form; whereas, the LacriCath is available as a procedure kit, or the kit components can be purchased separately from Quest Medical, Inc. The OphtaCath® Unilateral Kit is substantially equivalent to the LacriCath Unilateral Kit in contents and accessory devices. The OphtaCath® and LacriCath unilateral kits each contain one lacrimal balloon catheter and an inflation device for the balloon catheter. The inflation devices contained in the OphtaCath® and LacriCath kits are Class I, 510(k) exempt devices when used with ophthalmic lacrimal balloon catheters; thus, a substantial equivalence determination is unnecessary since these devices are exempt from premarket notification.

The Flamingo Inflation Device that is used with the OphtaCath® was originally cleared for marketing for use as an inflation device with cardiovascular balloon catheters as the Sedat Flamingo, 510(k) Premarket Notification Number: K082755, FDA Product Code MAV, Class II.

Subsequently, the trade name was modified to Flamingo Inflation Device, and the product line was extended to add the indication for use as an inflation device for ophthalmic lacrimal duct catheters under Product Code HNW, Class I, 510(k) exempt. The Flamingo Inflation Device for use with cardiovascular balloon catheters (product reference # 0218ND) is the exact same device as the Flamingo Inflation Device for ophthalmic lacrimal balloon catheters (product reference # 0275ND), and the devices in each product reference number are identical in every respect, except that the instructions for use contained in each package contains only the respective indication for use to assure maximum safe use of the device.

Similarly, the Atrion QL® Balloon Catheter Inflation Device was originally cleared for marketing under 510(k) Premarket Notification Number: K972964, FDA Product Code KOE, Subsequent Product Code HNW. The ophthalmic indication for use with lacrimal balloon catheters was added to the device, and FDA subsequently assigned Product Code HNW to the Atrion QL® device and rendered it Class I, 510(k) exempt status for the ophthalmic indication.

General Description

The OphtaCath® lacrimal duct catheter is a sterile and single-use balloon catheter consisting of a semi-flexible stainless steel stylet covered by PBX tubing that ends with a nylon balloon. The balloon is covered by a protective polyethylene sleeve. The balloon is designed to be inflated to a known diameter and length at the specified pressure. Markings are placed at 10 mm and 15 mm proximal to the working portion of the balloon. The overall length of the catheter is approximately 240 mm long. The catheter is available in a 2 mm and 3 mm inflated diameter. The 2 mm balloon has a length of 13 mm and a diameter of 0.90 mm before inflation. The 3 mm balloon has a length of 15 mm and a diameter of 1.0 mm before inflation.The Flamingo Inflation Device is an accessory to the OphtaCath®, and is a sterile, single-use inflation device for dilating the balloon catheter, monitoring balloon pressure, and deflating the balloon postoperatively.

The OphtaCath® is sold as a unilateral kit that contains one 2 mm or 3 mm balloon catheter and an inflation device (OphtaCath® Unilateral Kits, 2-mm and 3-mm).

Intended Use/Indications for Use

The intended use for the OphtaCath® is the same as for the LacriCath predicate device. The OphtaCath® and LacriCath devices (2-mm and 3-mm) are both indicated for use for the treatment of nasolacrimal duct obstruction; and, the LacriCath is also indicated for use for the treatment of dacryocystocele. These differences in the indications for use have no impact on the safety and effectiveness of the device itself. Unlike the LacriCath, the OphtaCath® indications for use statement contains the recommended balloon diameters based on age, which aids in proper device selection.

- The *OphtaCath® Unilateral Kits (2-mm and 3-mm)* are intended for use during dilation of the obstructed nasolacrimal duct to treat epiphora in patients 12 months of age and older. For patients older than 12 months but under 30 months, the recommended catheter is the 2 mm balloon diameter. For other patients 30 months or older, the recommended catheter is the 3 mm balloon diameter.

Comparison of Technological Characteristics
The OphtaCath® and LacriCath balloon catheters are sterile, single-use balloon catheters. As shown in the table below, the OphtaCath® (2-mm and 3-mm) has the same, or similar, technological characteristics, as the LacriCath (2-mm and 3-mm) predicate device.

	LacriCath Predicate Device (K113867)	**OphtaCath®**
Manufacturer	Quest Medical, Inc.	FCI SAS
Balloon Material	Nylon	Nylon
Stainless Steel Core/Stylet	304 Stainless steel core	304 Stainless steel stylet
Nominal Fill Pressure	8 atm	8 atm
Balloon Size	Diameter Length 2 mm 13 mm 3 mm 15 mm	Diameter Length 2 mm 13 mm 3 mm 15 mm
Balloon Diameter	Deflated Inflated 0.8 mm 2 mm 0.9 mm 3 mm	Deflated Inflated 0.9 mm 2 mm 1.0 mm 3 mm
Catheter Length	200 mm	240 mm
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterile Packaging	Tyvek peelable pouch	Tyvek peelable pouch
Unilateral Kit Accessory	Inflation device	Inflation device

The predicate device is also available in a 5 mm balloon diameter, whereas, the OphtaCath® is only available in the 2 mm and 3 mm sizes.

Brief Summary of Non-Clinical Tests and Results
The manufacturing process was validated, and demonstrated the capacity of FCI to manufacture the OphtaCath® lacrimal balloon catheter. Bench top testing was performed on samples before and after sterilization to validate the flexibility of the stylet, deflation time, compliance, and burst of the catheter and its components. All nonclinical test results met the established specifications for the device. Test results demonstrate that the OphtaCath® catheter did not contain any leakages while being inflated and all welds were of sufficient tensile strength to resist breakage.The biocompatibility of the balloon raw materials and finished, sterilized device was tested to the applicable standards and met required specifications. Ethylene oxide sterilization validation studies and package integrity studies were performed according to the applicable standards; and, the test results support the shelf-life and storage conditions for the device. The assembly of the balloon catheter with the inflation device was tested and validated to demonstrate the connectivity of the kit components and the fluid fill volume of the inflation device. Test results demonstrate the compatibility of the components.

From the testing, it can be concluded that the OphtaCath® lacrimal balloon catheter performs as intended without leakage or breakage; and that the assembled device performs as intended.

Basis of Substantial Equivalence

The OphtaCath® lacrimal balloon catheter is substantially equivalent to the LacriCath lacrimal balloon catheter in material, intended use, basic design concept, dimensions, sterilization methods, performance testing, biocompatibility and clinical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 29, 2013

FCI SAS (France Chirurgie Instrumentation)
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President
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Upper Level
Cincinnati, OH 45220

Re: K123831
Trade/Device Name: OphtaCath® Unilateral Kit
Regulation Number: None
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: June 19, 2013
Received: June 19, 2013

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K123831

Device Name: OphtaCath Unilateral Kit

Indications for Use:

The OphtaCath® Unilateral Kits (2-mm and 3-mm) are intended for use during dilation of the obstructed nasolacrimal duct to treat epiphora. For patients older than 12 months but under 30 months, the recommended catheter is the 2 mm balloon diameter. For patients 30 months and older, the recommended catheter is the 3 mm balloon diameter.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X_____ OR Over-The-Counter Use _____

James P. Bertram -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number___K123831_____